Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
11-21-2001	Central Meat Control Laboratory

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Dept. of Agriculture, Food and Rural Development	Dublin, Ireland	Abbotstown, Dublin, Ireland

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Dr. Paul Rafter

	REVIEW ITEMS	ITEM #	EVALUATION CODE	Residue Code/Name ▶ abc	cap	tet	hm	hor	B-ag						
SAMPLING PROCEDURES	Sample Handling	01		A	A	A	A	A	A						
	Sampling Frequency	02		A	A	A	A	C	C						
	Timely Analyses	03		A	A	A	C	C	A						
	Compositing Procedure	04		O	O	O	O	O	O						
	Interpret Comp Data	05		O	O	O	O	O	O						
	Data Reporting	06		A	A	A	A	A	A						
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	RIA						
	Correct Tissue(s)	08		A	Urine	A	A	Urine ser	ret-ina						
	Equipment Operation	09		C	A	C	A	A	A						
	Instrument Printouts	10		C	A	C	A	A	A						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A						
	Recovery Frequency	12		A	A	A	A	A	A						
	Percent Recovery	13		A	A	A	A	A	A						
	Check Sample Frequency	14		A(c)	A	A(c)	A	A	A						
	All analyst w/Check Samples	15		A(c)	A	A(c)	A	A	A						
	Corrective Actions	16		C	C	C	C	C	C						
	International Check Samples	17		O	O	O	A	O	O						
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	C	C	C	C	C	C						
OTHER REVIEW		19	EVAL. CODE												
		20	EVAL. CODE												

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW	Date: 11/20/01	Name: Central Meat Control Laboratory

FOREIGN GOV'T AGENCY: Dept. of Agriculture, Food, and Rural Development, Dublin, Ireland

AUDITOR: Dr. Gary D. Bolstad | **FOREIGN OFFICIAL:** Dr. Paul Rafter

RESIDUE	ITEM	COMMENTS
Hormones, ß-agonists	02	For most classes of compounds, the number of analyses to date was within expectations with regard to the national residue testing plan. For beta-agonists, however, 2,040 samples were to be taken during the calendar year, but as of the end of September, only 649 samples had been completed. It was noted that the outbreak of Foot-and-Mouth Disease early in the year had caused hardships with meeting the projected quotas.
Heavy metals, hormones	03,18	Turnaround times (the amount of time from reception in the laboratory until the analyses are complete) for heavy metals were as long as 8 to 10 months, and for stilbenes two months. FSIS expects turnaround times of one month. The laboratory director explained that the section of the laboratory housing the equipment for heavy metals had been under extensive construction since early in the year, and that timely analysis would soon resume. Turnaround times had been found deficient for all classes of compounds during the previous FSIS audit of this laboratory (4/28/2000); the turnaround times were now within expected limits for all other classes.
Antibiotics, Tetracyclines	9,10	No confirmatory testing for antibiotics and tetracyclines had been performed since January 2001 on field samples that had tested positive on screening tests. Carcasses that had been sampled as a result of suspicion of residues (with tentative injection sites) and that had tested positive on the antibiotic screening test were condemned. Positive samples from carcasses sampled randomly were being held until confirmatory methods would be in place; this was expected to occur within the next 6 to 12 months. There had been very few (six) positive random samples since the start of the calendar year.
Antibiotics, Tetracyclines	13	No percent recoveries were available for antibiotics or tetracyclines, because the confirmatory tests were under development (see items 9, 10 above).
All	14,15, 18	FSIS requires that each analyst must participate in a check sample program, at least once per calendar month, for each class of substances for which he/she performs the field analyses for the national residue testing program. No intra-laboratory check samples were being performed for any of the compounds requiring radioimmune assay (stilbenes, beta-agonists, chloramphenicol, and sedatives) or for antibiotics. The laboratory director explained that a source of reference material containing known amounts of these compounds was being sought, and that a potential source had been located in Trieste, Italy. Also, a permanent quality assurance (QA) manager and four additional technicians were expected to be added to the staff within six weeks, so that the requirements were expected to be met within several months. International check samples for heavy metals were analyzed every four months. Intra-laboratory check samples were provided to analysts for the screening tests, prepared from past positive samples, but none for quantitative analysis.
16	All	This laboratory had been functioning without a QA manager for more than two and a half years. A new acting QA manager had been in place for the past 3-4 months, but no written corrective action program had as yet been developed. This person was aware of the requirement and expected to have one implemented within the next six months.
		Note: In all sections of the laboratory, deficiencies noted during the previous FSIS audit regarding the standards books had been addressed and corrected.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
11-14-2001	Microchem Laboratories

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Private Laboratory	Dungarvan, County Waterford, Ireland	Clogherane, Dungarvan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Dr. Montse Gutierrez

	Residue Code/Name ▶			Sal	Ecol
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE		
	Sample Handling	01		A	A
	Sampling Frequency	02		A	A
	Timely Analyses	03		A	A
	Compositing Procedure	04		C	C
	Interpret Comp Data	05		C	C
	Data Reporting	06		A	A
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A
	Correct Tissue(s)	08		A	A
	Equipment Operation	09		O	O
	Instrument Printouts	10		O	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O	O
	Recovery Frequency	12		O	O
	Percent Recovery	13		O	O
	Check Sample Frequency	14		A	A
	All analyst w/Check Samples	15		A	A
	Corrective Actions	16		A	A
	International Check Samples	17		A	A
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O
OTHER REVIEW		19	EVAL. CODE		
		20			

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE	NAME OF FOREIGN LABORATORY
	11-14-2001	Microchem Laboratories

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Private Laboratory	Dungarvan, County Waterford, Ireland	Clogherane, Dungarvan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Gary D. Bolstad	Dr. Montse Gutierrez

RESIDUE CODES	ITEM NO.	COMMENTS
Both	04	Samples may be composited if so requrested by individual clients. The laboratory personnel available on the day of the audit did not know whether the establishments listed for U.S. export fell into this category.